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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,782	04/12/2001	D. Wade Walke	LEX-0161-USA	1934

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,782

Applicant(s)

WALKE ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: copy of the reference in PTO-892.

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Amendment and Response to Office Action filed on Nov. 7, 2002 as paper No. 12 is acknowledged.

The amendments to the claims have been entered as requested. Claim 2 is amended. Claims 4 and 5 are added. Claims 1-5 are pending in the application and are the subject of this Office Action.

Detailed Action

1. Rejections

1.1. 35 USC section 101

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention lacks specific and substantial utility for the reasons set forth in the prior Office Actions, Paper No. 8 and 10, and reiterated below.

In their response Applicants argue that utility of DNA molecule of SEQ ID NO: 1 is supported by the fact that it encodes SEQ ID NO: 2 that is identical to human neurolysin sequence disclosed by Chen et al., accession no. CAC27329, submitted to EMBL Jan 23, 2001, i.e., after 04/12/2000, which is the effective filing date for the instant application. The fact that the third party scientists cloned the human neurolysin gene and disclosed the amino acid sequence of the enzyme after the Applicant filed the application does not change the fact that the protein of SEQ ID NO: 2 encoded by DNA of SEQ ID NO: 1 was disclosed by Applicants as "a protein sharing sequence similarity with mammalian neurolysin proteins" (page 1, line 10), without quoting the percentage of homology to any mammalian neurolysin known at the time the application was filed. The phrase "sharing sequence similarity with mammalian neurolysin proteins" is not the

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statement of function, but it refers to the structure of the claimed chemical compound. At the time application was filed the function of neurolysin was well established for mammals, as Applicants proved by the content of the IDS. The characteristic features of neurolysin is that it cleaves neurotensin between residues Pro10 and Tyr11, and that it binds angiotensin. However, Applicants themselves did not present any evidence that protein of SEQ ID NO: 2 is able to cleavage neurotensin between residues Pro10 and Tyr11, and to bind angiotensin; the assays easy to perform *in vitro*.

Claims 1-3 and new claims 4-5 are also rejected under 35 USC § 112, the first paragraph, for the reasons stated in Office Actions No. 8 and 10. Since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention, so that it would operate as intended, without undue experimentation.

In their traverse of this rejection under 35 USC § 112, the first paragraph, Applicants submit, "that the claims have been shown to have specific, substantial, credible and well established utility, as detailed in section III above [because Applicants have presented the third party's data obtained after filing the instant application, MW]."

Applicants' argument has been fully considered but is found not persuasive. Applicants did not show that the claims have specific, substantial, credible and well-established utility. That are Chen et al. who demonstrated that human protein having

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the amino acid sequence as set forth in SEQ ID NO: 2 is neurolysin and has specific, substantial, credible and well established utility.

1.2. 35 USC section 112, second paragraph

Rejection of Claim 2 made in the previous Office Action, paper No. 10, is withdrawn because the claim has been amended.

New Claim 5 is rejected as improperly dependent from itself.

1.3. 35 USC section 112, first paragraph

New rejection of claim 2 under this paragraph made in the previous Office Action, paper No.10, is withdrawn because it was improper.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meliorate A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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